



























# **EXHIBIT 4**




Cautions	9	EMC Guidelines	10	Symbols	11																	
<div>PROCESSING CAUTIONS</div> <div>When the CAM is returned to the processing center, these additional cautions apply.</div> <div><div></div><div><b>CAUTION: Contaminated surfaces</b> When the CAM is returned to the reading center, it will have been in contact with human skin. Follow the facility's procedures for appropriate handling.</div></div> <div><div></div><div><b>CAUTION: Battery may present environmental hazard</b> The CAM contains a battery. Properly dispose of batteries in accordance with local regulations.</div></div> <div><div></div><div><b>CAUTION: Electronic waste may present environmental hazard</b> The CAM is considered medical electrical equipment. Properly dispose of electronic waste in accordance with local regulations.</div></div> <div><div></div><div><b>CAUTION: Single use only</b> The Bardy Diagnostics CAM is not intended for reuse, as the monitor becomes non-functional after the first use.</div></div>		<div>EMC GUIDELINES</div> <div>The CAM requires special cautions regarding EMC and needs to be put into service according to provided information.</div> <div><div></div><div><b>CAUTION: Electromagnetic interference (EMI)</b> Portable and mobile wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect the CAM and should be kept at least a distance of 30 centimeters away from the equipment. Position the CAM away from other electrical or electronic equipment, if possible. The presence of strong EMI fields, or electronic, surgical, or diathermy instruments in close proximity to the ECG device may cause trace noise or input overload conditions.</div></div> <div>The ECG device is compliant with IEC 60601-1-2 EMC immunity requirements.</div>		<div>SYMBOLS</div> <div>Bardy Diagnostics products display one or more of these symbols and warning labels.</div> <table><thead><tr><th>SYMBOL</th><th>DESCRIPTION</th></tr></thead><tbody><tr><td></td><td>Attention: Consult accompanying documents</td></tr><tr><td></td><td>Warning and caution symbol</td></tr><tr><td></td><td><div>TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of 60601-1 to provide a higher degree of protection against electronic shock than that provided by TYPE B APPLIED PARTS.</div><div>Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.</div></td></tr><tr><td>IP23</td><td>Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical. Do not immerse in bathtub or swimming.</td></tr><tr><td></td><td><div>Sold by prescription only</div><div><b>CAUTION:</b> Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.</div></td></tr><tr><td></td><td>Single use only</td></tr><tr><td></td><td>Manufacturer</td></tr><tr><td></td><td>Use-by date</td></tr></tbody></table>	SYMBOL	DESCRIPTION		Attention: Consult accompanying documents		Warning and caution symbol		<div>TYPE BF APPLIED PART: F-TYPE APPLIED PART complying with the specified requirements of 60601-1 to provide a higher degree of protection against electronic shock than that provided by TYPE B APPLIED PARTS.</div> <div>Note: TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.</div>	IP23	Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical. Do not immerse in bathtub or swimming.		<div>Sold by prescription only</div> <div><b>CAUTION:</b> Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.</div>		Single use only		Manufacturer		Use-by date
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Symbols	12	Technical Specifications	13	Technical Specifications	14																	


SYMBOL	DESCRIPTION
	Do not expose to temperatures outside of these limits. For more information on environmental parameters refer to the Technical Specifications section.
	Atmospheric pressure must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
	Humidity must be within these limits. For more information on environmental parameters refer to the Technical Specifications section.
	Date of manufacture
	Contains electronic equipment. Dispose of properly in accordance with local regulations.
	Serial number
	Orderable part number
	Batch code
	MR Unsafe

**TECHNICAL SPECIFICATIONS**


ITEM	SPECIFICATION
<b>Performance Characteristics</b>	
ECG channels	1 channel
Recording capacity	Up to 2, 7, or 14 days
Recording format	Continuous
Service life	Up to 2, 7, or 14 days
Shelf life	24 months
<b>Electrical Characteristics</b>	
Frequency response	0.67 Hz to 25 Hz
Differential range	4 mV
A/D sampling rate	171 Hz
<b>Power Requirements</b>	
Battery type	Lithium primary (coin cell)
Lithium content	Lithium content < 1 g
Heavy metal content	Within weight limits of 2006/66/EC
UN compliance	Complies with UN 3090

ITEM	SPECIFICATION
<b>Physical Characteristics</b>	
Approximate dimensions	178mm x 38mm x 14mm
Weight	<25g
Enclosure material	Medical grade thermoplastic polymer
Flammability rating	UL-HB
<b>Classification</b>	
Type of protection	Internally powered
Degree of protection	Type BF applied part
Protection against objects and water ingress	IP23 (Protected against intrusion from fingers and small objects, and from water falling as a spray at an angle of up to 60° from vertical)
<b>Electrode Characteristics</b>	
Number of electrodes	2
Type	Electrode incorporating electrode gel and internal lead wire
Supplied as	Disposable, non-sterile
Lead wire length	11.6 cm (no patient contact)
Materials	Electrode gel: Medical grade conductive synthetic Adhesive: Medical grade skin adhesive


Technical Specifications		15	 Carnation Ambulatory Monitor®
<b>Environmental Specifications (ECG Device)</b>			
Operating temperature	50° F to 113° F (10° C to 45° C)		
Operating pressure	700 to 1060 hPa		
Operating humidity	10% to 95% (non-condensing)		
Transport temperature	14° F to 130° F (-10° C to 55° C)		
Storage temperature	59° F to 77° F (15° C to 25° C)		
Transport / Storage humidity	10% to 95% (non-condensing)		
Transport / Storage pressure	500 to 1060 hPa		
Standards compliance	Applicable sections of IEC 60601-1, 60601-1-2, 60601-1-11, 60601-2-47		




**BardyDx®**  
*We're close to your heart®*



**Bardy Diagnostics, Inc.®**  
220 120th Avenue NE, Ste 100  
Bellevue, WA 98005  
USA  
US Customer Service:  
(844) 777-9283

 By prescription only

 Read all instructions  
before using this product


This device is provided non-sterile.

[www.bardydix.com](http://www.bardydix.com)

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# Instructions For Use

For additional instructions and  
Frequently Asked Questions  
visit [www.bardydix.com](http://www.bardydix.com)



## Electromagnetic Emissions Declarations

## Guidance and manufacturer's declaration – electromagnetic emissions

The CAM is intended for use in the electromagnetic environment specified below. The customer or the user of the CAM should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The CAM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group B	The CAM has No AC Mains, and is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

## Guidance and manufacturer's declaration – electromagnetic immunity

The CAM is intended for use in the electromagnetic environment specified below. The customer or the user of the CAM should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3  Radiated RF Proximity Fields IEC 61000-4-3 (per IEC 60601-1-2 Ed.4)	10 V/m 80 MHz to 2,7 GHz  9 V/m - 28 V/m per IEC 60601-1-2 Ed.4, Table 9	10 V/m 80 MHz to 2,7 GHz  9 V/m - 28 V/m per IEC 60601-1-2 Ed.4, Table 9	Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the CAM.  Interference may occur in the vicinity of equipment marked with the following symbol: 